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The increasing use of electronic prostheses in a society where the numbers and intensities of radiofrequency (RF) radiation sources are ever increasing requires special attention by the manufacturers of the medical devices and the practicing physicians who prescribe these devices. One such device, the artificial cardiac pacemaker, was tested extensively to assess the extent of radiofrequency electromagnetic radiation interference (EMI) possible from a variety of RF sources. Pacemaker responses were measured on twenty-one

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20. ABSTRACT (Continued)

different types (manufacturers and models) of devices, exposed in "free-field" and "simulated-implant" configurations. Relative interference thresholds were vastly different;the most sensitive pacemaker being adversely affected at electric (E) field levels as low as 10 volts per meter and the least sensitive pacemaker being relatively free of interference at levels as high as several hundred volts per meter. In many cases the real time E-field level around radiofrequency radiation (RFR) emitters manifests itself as a pulsed or pseudo-pulsed (changing E-field) signal which can adversely affect cardiac pacemakers and is potentially hazardous for other types of medical prosthetic devices. These empirical findings demonstrate the need for continuing awareness of potential RF interference situations and provide reasonable evidence that through such awareness many of the potential EMI problems can be effectively circumvented

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EMC DESIGN EFFECTIVENESS IN ELECTRONIC MEDICAL PROSTHETIC DEVICES

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ABSTRACT

The increasing use of electronic prostheses in a society where the numbers and intensities of radiofrequency (RF) radiation sources are ever increasing requires special attention by the manufacturers of the medical devices and the practicing physicians who prescribe these devices. One such device, the artificial cardiac pacemaker, was tested extensively to assess the extent of radiofrequency electromagnetic radiation interference (EMI) possible from a variety of RF sources. Pacemaker responses were measured on twenty-one different types (manufacturers and models) of devices, exposed in "free-field" and "simulated-implant" configurations. Relative interference thresholds were vastly different with the most sensitive pacemaker being adversely affected at electric (E) field levels as low as 10 volts per meter and the least sensitive pacemaker being relatively free of interference at levels as high as several hundred volts per meter. In many cases the real time E-field level around radiofrequency radiation (RFR) emitters manifests itself as a pulsed or pseudo-pulsed (changing E-field level) signal which can adversely affect cardiac pacemakers and is potentially hazardous for other types of medical prosthetic devices. These empirical findings demonstrate the need for continuing awareness of potential RF interference situations and provide reasonable evidence that through such awareness many of the potential EMI problems can be effectively circumvented.

Introduction

Technics for designing equipment for electromagnetic radiation compatibility (EMC) are applied rather extensively throughout a large segment of the electronics industry. Recent studies indicate such technics are now being effectively incorporated in the design of medical prosthetic devices such as the artificial cardiac pacemaker. The test results reported in this paper demonstrate the success of many manufacturers in eliminating or circumventing the unwanted electromagnetic interference sensitivity common in many of the earlier pacemaker designs.

The fact that external interference can disrupt the normal operation of some cardiac pacemakers has been recognized almost since the first unit was placed in service, but at the same time, practicing clinicians have generally maintained that such interference is not clinically significant (15). Notwithstanding these facts, the manufacturers have apparently recognized the sources of potential interference are ever increasing and they have included EMI as one of many design considerations in their newer devices.

In regard to the overall interference aspect, EMI tests generally establish the "relative sensitivities" of the pacemakers on the market at some particular time, under certain test conditions. Examples of such studies are referenced (4, 9, 10, 13, and 16). A current study of the relative EMI characteristics of the newer pacemakers as compared to previous designs for several different types of radiation sources follows.

Materials and Methods

Seventy pacemakers including 10 manufacturers and 21 different designs as listed in Table 1 were tested. Radiation sources included laboratory generators operating at pulsed frequencies of 450 MHz and 3100 MHz; such electric devices as sabre saws, variable speed drills, food mixers, hair dryers, pocket calculators, garage door openers, and razors; and the RF emission from an automobile ignition. Additional devices such as lawn mower and motorcycle ignition systems, portable radio transmitters, outboard motors, diathermy machines, and certain communication and radar devices will also be used in this test series in the next few months.

The pacemakers were tested in both free-field and simulated-implant configurations for each of the radiation sources. For the free-field configuration the pacemakers and leads were mounted on a lucite stand. For the simulated implant configuration the lucite stand was placed in the phantom (20 x 30 x 30 cms) filled with 0.03 molar saline solution, being careful to locate the pacemaker to

TABLE I. Cardiac pacemakers included in these tests

Manufacturer	Model	
American Optical	281003	
American Optical	281013	
American Optical	281143	Predicta Series
Biotronik	IDP44	
Cordis	133C6	Atricor
Cordis	133C7	Atricor Jr.
Cordis	143E7	Stanicor
Cordis	162C	Omni-Stanicor
Cordis	164A	Omni-Atricor
General Electric	A2072D	
General Electric	A2075A	Sentry Series
Medcor	3-70A	
Medtronic	5842	
Medtronic	5942	
Medtronic	5943	
Medtronic	5944	
Medtronic	9000	Nuclear
Pacesetter	BD101	Rechargeable
Starr-Edwards	8114	
Starr-Edwards	8116	Ventrac
Stimtech	3821	
Vitatron	MIP40RT	

position one cm of solution between the pacemaker and the wall of the phantom. The phantom wall thickness was 1.5 mm and its measured attenuation of the RF field was negligible. Pacemaker response was recorded via a fiber optics monitoring system consisting of a light emitting diode (LED) mounted in a subminiature audio plug, loaded with a network to maintain 600 ohms, ten feet of sheathed light pipe coupled to a photoresistive voltage dividing network, a Mennen Greatbatch amplifier, and a dual channel strip chart recorder.

The 450 MHz and 3100 MHz tests were conducted in an anechoic chamber at the Georgia Institute of Technology Engineering Experiment Station (GIT), Atlanta, Georgia. The 450 MHz tests were conducted with pulse widths of one microsecond to one millisecond and pulse repetition rates of 2, 10, 20, 40, and 50 pulses per second (pps) to circularly polarized E-field intensities up to 292 volts per meter (V/m). The 3100 MHz tests were conducted at pulse widths of 10-120 microseconds and pulse repetition rates of 7, 10, 20, 40, 100, 200, and 400 pps to vertically polarized E-field intensities up to 320 V/m (rms). The E-field levels to which the pacemakers

were exposed were measured by both GIT personnel and by personnel from the Air Force Communication Service, 1839 Electronic Installation Group, Keesler AFB, Mississippi.

The appliance tests were conducted in the USAFSAM Radiation Science Laboratory, Brooks AFB, Texas. Measurements of the radiofrequency radiation emission of the appliances have not been completed so the pacemaker effects were recorded as a function of distance from the respective appliances.

Test Results

Table II is a summary of the adverse effect thresholds of each pacemaker model tested in the simulated-implant configuration at 450 MHz. An adverse effect is defined as a pacemaker rate which falls below 50 beats per minute (bpm) or exceeds 120 bpm as a direct result of RF radiation interference. In most instances the value at which the most sensitive of so-called identical pacemakers cut off completely was selected as the adverse effect threshold. In cases where the threshold is based on an increased rate, it was generally observed that the pacemaker rate continued to increase with increasing E-field level. Where no adverse effect was observed at the maximum E-field level available, it is noted by >292 V/m. Blank spaces indicate the other data points are adequate to describe the effect.

The test data summarized in Table II serve to illustrate the wide range (8 V/m to >292 V/m) of EMI susceptibility thresholds among the 21 pacemaker models tested. Comparing the relatively new A.O. pacemaker (item No. 3) with the older A.O. models (Nos. 1 and 2) shows a dramatic improvement in EMI characteristics. The same is true for the new Starr-Edwards model 8116 compared to their model 8114. It is also noteworthy that the Pacesetter pacemaker marketed this past year was not affected by the maximum E-field available indicating that EMI characteristics were considered during the design stages. Again as in tests conducted two years ago, the Biotronik pacemakers (obtained just prior to these tests) maintained good EMI characteristics. Although the improvements in EMI characteristics were much greater for some models, it appears that all of the manufacturers are including EMI as a design consideration and in essentially every case the newer models show improvement in this respect.

The data in Table II also illustrate that some of the pacemakers revert to their interference rejection mode (fixed rate) upon sensing interference at pulsed rates as low as 10 pps while some others revert at a much higher pulse rate. Very few effects were noted at 3100 MHz since the implanted adverse effect thresholds were all greater than 200 V/m with only 4 of the 21 pacemaker types being significantly affected at 320 V/m.

TABLE II. Summary of adverse effects thresholds recorded during simulated-implant tests

	450 MHz, 1 msec PW			
	Pulse Repetition Rate (pps)			
	2	10	20	40
	V/m(bpm)	V/m(bpm)	V/m(bpm)	V/m(bpm)
1. A.O. 281003	13(0)		15(0)	243(0)
2. A.O. 281013	23(0)		26(0)	243(0)
3. A.O. 281143	>292	>292		>292
4. Biotronik IDP44	141(0)	>292		>292
5. Cordis Atricor	>292	>292		141(172)
6. Cordis Omni-Atricor	>292	>292		>292
7. Cordis Stanicor	15(0)	15(0)	243(24)	>292
8. Cordis Omni-Stanicor	8(0)	9(0)	9(0)	>292
9. G.E. A2072D	29(0)	207(122)		
10. G.E. A2075A	23(0)	141(125)		
11. Medcor 3-70A	29(0)	141(0)	141(0)	141(0)
12. Medtronic 5842	15(0)		15(0)	13(0)
13. Medtronic 5942	12(0)			12(0)
14. Medtronic 5943	23(0)		19(0)	>292
15. Medtronic 5944	26(0)	36(0)	207(400)	207(400)
16. Medtronic 9000	10(0)	10(0)	12(0)	>292
17. Pacesetter BD101	>292	>292	>292	>292
18. Starr-Edwards 8114	23(0)	26(0)	>292	
19. Starr-Edwards 8116	>292	>292	>292	>292
20. Stimtech 3821	107(0)	114(0)	>292	>292
21. Vitatron	93(0)	107(0)	243(0)	243(0)

Although the "free-field" results are not presented, the "free-field" to implant attenuation factors using the phantom with one cm of solution were ∿3 at 450 MHz based on the pacemaker response data and ∿5 at 3100 MHz based on antenna measurements by GIT personnel.

The effect of "pulse-width" was also studied indicating that one might expect a higher E-field response threshold for shorter pulse widths (less than one millisecond) for some pacemakers. In this regard it should be noted that the 3100 MHz data were taken with a 120 microsecond pulse width.

A cursory evaluation of the effect of leads was also made. For instance, the data presented for the Medtronic and A.O. pacemakers were taken using the Medtronic model 6914 epicardial leads.

Switching to the model 5818 endocardial leads appears to raise the E-field thresholds somewhat for the Medtronic pacemakers, but did not change the effect on the A.O. devices. However, the lower threshold values are reported based on the fact that many of the model 6915 epicardial leads are probably still in use and because we believe it is highly probable that many of these model pacemakers would likely have response thresholds as low as the three devices making up our basic test sample.

Table III is a summary of the response of the pacemakers when subjected to the indicated sources of RF radiation emission. These tests were conducted with the pacemakers in the saline solution phantom and the sources located at 2, 10, 25, 50, and 100 cms from the phantom. These data represent the worst case effect, and in all instances it was within 25 cms of the source. The Roman numerals grade the pacemaker response:

I - No apparent change in pacemaker rate;
II - Intermittent change in rate, e.g., missing 1 or 2 beats periodically;
III - Steady rate between 50 bpm and 120 bpm;
IV - Rate is less than 50 bpm or greater than 120 bpm; and
V - Cut off, misses more than five consecutive beats.

The fact that many different types of RF radiation emitters can disrupt the normal operation of some pacemakers is well known and is covered in most of the manufacturers' literature provided to patients. These tests confirm the fact that, in general, sources of interference such as elecric razors, drills, and food mixers must be very close to the pacemaker to result in any significant interference.

CONCLUSIONS

Electromagnetic RF radiation having a field intensity above a certain threshold value (dependent on the specific pacemaker) can mimic the ventricular activity (R-wave signal) of the heart, thus resetting the demand pacemaker timing circuit, so that a pacemaker impulse is not provided until a certain escape interval has elapsed. The extent or significance of such interference (EMI) is primarily dependent on the envelope of the E-field gradient as a function of time. If the E-field intensity is changing in such a manner to mimic a pulse repetition rate of $\sim$1 to $\sim$10 pps with the peak of each pulse above the pacemaker's interference threshold, the pacemaker will inhibit (cut off). If the effective pulse repetition rate is greater than some inherent value (specific to each device), the pacemaker may revert to its interference rejection mode (fixed rate). Reversion to fixed rate is judged nonhazardous. Inhibition

TABLE III. Summary of pacemaker response to indicated sources in the simulated-implant test configuration

	Sabre Saw	Variable Speed Drill	Food Mixer	Hair Dryer	Pocket Calculator	Garage Door Opener Alliance	Electric Razor	Volkswagen Automobile Ignition
A.O. 281003	II	I	II	II	I	II	V	V
A.O. 281013	II	II	II	II	V	II	III	V
A.O. 281143	I	I			I	I		I
Biotr. IDP-44	II	II	I	I	I	I	I	III
Cordis 133C7	III	III	III	III	I	III	III	IV
Cordis 143E7	II	II	II	II	I	II	V	V
Cordis 162C	III	V	II	II	I	II	II	V
Cordis 164A	I	I	III	III	I	III	III	III
G.E. A2072D	II	IV	I	I	I	I	III	IV
G.E. A2075A	IV	V	II	II			V	V
Medcor 3-70A	II	I	V	I	I	I	III	IV
Medtr. 5842	V	II	II	II	I	II	V	V
Medtr. 5942	II	II	II	II	I	I	I	V
Medtr. 5943	III	I	II	I	I	I	I	V
Medtr. 5944	I	I	I	I		I	I	III
Medtr. 9000	I	I	II	I	I	I	I	II
Paces. BD-101	I	I			I	I		
Starr-Ed. 8114	II	V	V	II	I	I	II	IV
Starr-Ed. 8116	II	V	II	II		II	II	III
Stimtech 3821	I	I			I	I	I	V
Vita. MIP-40-RT	I	I	I	I	I	I		II

is judged hazardous. Some of those pacemakers tested reverted to their fixed rate at any pulse repetition rate above 5 pps, while others would not revert at pulse rates as high as 40 pps.

Although these tests reflect remarkable abilities of some manufacturers to essentially solve the potential interference problem, the data also show some currently marketed devices still have adverse effect thresholds at E-field levels likely to be found

around RF sources in areas accessible to the general populace. These current tests validate previous test results; i.e., the most effective interference frequency appears to be between 200 MHz and 600 MHz. The adverse effect thresholds at 450 MHz ranged from ∿8 V/m to >292 V/m.

A cursory examination of the effect of the pulse width of the incident radiation indicates at 3100 MHz that decreasing the pulse width from 120 microseconds to 10 microseconds raises the E-field threshold on some pacemakers by a factor of ∿3; and at 450 MHz decreasing the pulse width from 1 millisecond to 1 microsecond increases the E-field threshold for some pacemakers by a factor of ∿25-35.

Measured shielding factors in the simulated-implant configuration (one cm of 0.03 molar saline solution) as compared to free-field are ∿3 at 450 MHz and ∿5 at 3100 MHz. Furthermore, the type of pacemaker leads used and the lead geometry can alter the E-field threshold by a factor of ∿2.

At the 3100 MHz frequency, using 120 microsecond pulse width, none of the pacemakers tested under simulated-implant conditions were seriously affected at an E-field level of 200 V/m.

At 450 MHz, the American Optical (A.O.) model 281143, Starr-Edwards model 8116, and Pacesetter model BD-101 were not affected at 200 V/m in the simulated-implant tests. The General Electric (G.E.) model A2072D, Biotronik model IDP-44, and Cordis Atricor pacemakers demonstrated no serious effects at 200 V/m for pulse repetition rates greater than 10 pps. All other pacemakers tested were seriously affected at E-field values below 200 V/m and pulse repetition rates greater than 10 pps.

In general, the pacemakers being marketed today as compared to those of two years ago offer considerably more resistance to electromagnetic interference. Also, it appears the total number of the more sensitive pacemakers in service two years ago has been reduced about 80%. Continuing effort by the manufacturers will ultimately resolve most of the potential pacemaker EMI problems, and it is hoped that the manufacturers of other medical instrumentation and electronic prostheses will incorporate good EMI rejection technics in all new devices.

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-DISCUSSION-

GRAMIAK - Did you test any therapeutic ultrasound devices?

MITCHELL - Very early in the program we checked several pacemakers near an ultrasound source at one of the local clinics. On the basis of these qualitative evaluations the ultrasound devices do not appear to represent any significant problem.

GLASER, Z. - Do you foresee any problems with those automobile, anti-collision radar devices that are being talked about?

MITCHELL - From what I know about these radars they operate at sufficiently high frequencies and should not represent any threat to pacemaker patients.

VOGELMAN - I just thought you might be interested in knowing that one of our patients has a pacemaker. It is the older model Medtronics, and at one foot from his power saw or at one foot from his calculator, the pacemaker is adversely affected. He has had some weakness problems as a result until we found out what was doing it.

MITCHELL - Two years ago we predicted and published the threshold level of interference on a Medtronics model 5842 at 450 MHz (pulsed) was a half volt per meter. A recent article in Circulation magazine discussed a case of an individual passing out in a parking lot due to interference from a TV tower, and when they measured the level it was a half volt per meter.

VOGFLMAN - Well, when this patient is more than an arms length from the source he is all right.

MITCHELL - I have numerous similar reports. It is real to the people who use pacemakers, and most particularly to those persons using the older, more sensitive models.

SUESS - I have two questions. In the slides you have shown, you have demonstrated or at least presented test data on deleterious effects from the pacemakers due to several types of electrical equipment. Would these effects result from a continuous or from a momentary failure?

MITCHELL - I should point out that as soon as any interference is removed or turned off the pacemaker resumes normal operation. It can interpret external signals as heart activity and properly inhibit when they are present.

SUESS - My second question relates to a short activity which took place last October in our office. One of the problems discussed was whether a pacemaker may hurt the man?

MITCHELL - Are you talking about possible electrical pick-up and subsequent harm to the user?

SUESS - Well, we may now have an increasing problem in urban areas created by electromagnetic fields from various sources. A pacemaker, even when well protected, still has the wiring and so on. Now, if a magnetic field is being produced there, and considering the probably growing number of people who may use pacemakers, we may face, to some extent, a public health problem. How would you look at this problem?

MITCHELL - The leads contribute to the interference but do not concentrate sufficient electrical fields to be harmful to the user.

SUESS - But what about the field created by the pacemaker and its wiring?

MITCHELL - Like a metal implant situation? We have considered that and do not consider it to be any problem under normal environmental exposures.

DUNN - A stupid question, but how does a calculator interfere?

MITCHELL - It has an oscillator that puts out a high frequency (pulsed) signal, but, it must be very close to the pacemaker to cause the effect.

VOGELMAN - Are there other electronic medical devices which might be EMI susceptible?

MITCHELL - Yes, devices like the brain pacemaker, the pain stimulation device, perhaps artificial organs, maybe even to some extent elaborate electrical control of arms and legs could possibly be affected.

FLOOR - But the blocking of one of those devices should be less serious than the blocking of the cardiac pacemaker. Don't you think?

MITCHELL - Yes.

FLOOR - Is there a reason for your choice of 450 and 3100 MHz or is it pure convenience?

MITCHELL - These frequencies were originally selected to meet an operational concern, but since then we have run tests for a broad frequency range down to about 30 kiloHertz, and up to 8 or 10 GHz. We find that the most sensitive frequency is somewhere between a hundred and 600 MHz. So the 450 MHz turns out to be a useful frequency. From a practical standpoint most pacemakers that show low EMI at this frequency do fairly good at most of the other frequencies.

ELY - Do you get a feeling for measurement or estimation of field strengths of any of these other interfering devices that would allow planning of the construction of a device. Suppose you are going to build a new drill or food mixer? Would you design it to emit less than so much?

MITCHELL - Probably not.

ELY - Or do you think the whole way to go is immunity of the patient --

MITCHELL - Well, it appears to me that the manufacturers are really solving the problem.

OSEPCHUK - I would like to comment that in the last few years the immediate reaction of some people to such interference is that the source is bad. Of course, as time goes on and almost every source becomes incriminated, the point finally dawns on some people that there may be something wrong on the other side, described by a word called susceptibility. You know, the military would never procure pacers the way they were designed with the transparent potting and absolutely no attention to RFI. Susceptibility doesn't need to be there. It

OSEPCHUK - turns out it is fairly easy to remove.

The reaction of some medical doctors to engineers' new pacer designs for reduced susceptibility is a fear of overkill. They imagine that the pacer will be so immune to RFI that they can't do things like using a transistor radio to pick up the pacer signal. I presume manufacturers all know that they still can do that, even with a shielded model - isn't that correct?

FLOOR - There is no fear for the MD's that you are going to have overkill or the pacer manufacturer is going to overkill this thing and prevent the MD's from doing what they want with it. There have been MD's who feel that the engineers are going to force this on them.

MITCHELL - I think there are some valid points on both sides of that argument. You never please everybody, but we hope somewhere along the way this thing will get resolved.